IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard T. Redano

Group Art Unit: 3762

Serial No.: 10/134,356

Examiner: R. Smith

Filed: April 27, 2002

Docket No.: REDA-100

For: Apparatus For Measuring Hemodynamic Parameters

Honorable Commissioner of Patents
Washington, D.C. 20231

**FIRST PRELIMINARY AMENDMENT**

Please amend the above referenced application as shown below.

IN THE SPECIFICATION

Please amend the specification by substituting the numbered paragraphs shown below for the paragraphs bearing these numbers in the specification. Marked up versions of the paragraphs appearing below appear in the Appendix showing the changes made by this amendment.

[0025] The apparatus of the present invention comprises an ultrasound generator 9 and a portable housing 10 coupled to the ultrasound generator, as shown in Figure 2. As shown in Figure 2, control mechanisms for regulating the transmission of ultrasound energy from the ultrasound generator are mounted on body 9, which is sized to be grasped or held in a user's hand. In a preferred embodiment, these control mechanisms include knob-like fixtures 6-7 which may be adjusted to regulate or control the frequency or intensity of ultrasound energy emitted by the ultrasound generator. The portable housing comprises a fist transducer mounting assembly 18. In a preferred embodiment, the first transducer mounting assembly is curved. An ultrasound trigger 11 is mounted in the housing and is electrically coupled to the generator. The ultrasound trigger 11 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasound source or emitters , as shown in Figures 2 and 3.

[0026] In a preferred embodiment, the ultrasound generator is capable of selectively generating pulsed or continuous wave ultrasound energy. The selective generation may be accomplished by

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a control knob or switch 8, as shown in Figure 2. In a preferred embodiment, the ultrasound generator further comprises frequency controls 6 and intensity controls 7, as shown in Figure 2. In a preferred embodiment, the ultrasound generator is capable of generating ultrasound energy within a frequency range of 1.8-3.5 MHz and within an intensity range of 1.0-2.0 watts/square centimeter.

[0029] The apparatus and method of the present invention may be practiced by the patient, after proper training, without assistance from another person. In the preferred embodiment shown in Figure 2, the portable housing has a pistol type grip, thereby allowing the user to operate the trigger or triggers with one hand, while manipulating the position adjuster with the other hand, as needed to maintain a suitable ultrasound coupling during penile expansion. As shown in Figure 2, the portable housing 10 is sized to be grasped or held in a user's hand. The placement of the triggers and axial position adjuster on opposite sides of the housing facilitates the user's ability to easily use both hands to simultaneously manipulate the trigger and the position adjuster.

[0030] In a preferred embodiment, the invention further comprises a second transducer mounting assembly 24 mounted across from the first transducer mounting assembly. As shown in Figure 2, the position adjuster permits the distance between housing 10 and mounting assembly 24 to be adjusted by the user using one hand. In the preferred embodiment shown in Figure 2, the mounting assembly 24 is moveably connected to the housing 10. In a preferred embodiment, the second transducer mounting assembly is mounted in alignment with the first transducer mounting assembly. In another preferred embodiment, the second transducer mounting assembly is curved. The second transducer mounting assembly is coupled to the position adjuster. In a preferred embodiment, the radii of curvature of the first and second transducer mounting assemblies are sized such that the first and second transducers can be coupled to the outer surface of a penis.

[0033] In the preferred embodiments shown in Figures 2-3, the invention further comprises an ultrasonography generator 30 connected to at least one transducer in each transducer mounting assembly and an ultrasonography trigger 12 mounted in the portable housing and connected to the ultrasonography generator. The ultrasonography trigger 12 is a triggering mechanism that

can be actuated to cause ultrasound energy to be transmitted from the ultrasonography generator and through the ultrasound source or emitters, as shown in Figures 2 and 3. In a preferred embodiment the ultrasonography generator and the ultrasound generator are each connected to at least two ultrasound transducers in each of the transducer mounting assemblies. In a preferred embodiment the ultrasonography generator is a doppler ultrasound unit.

[0034] The ultrasonography generator is suitable for monitoring penile hemodynamic parameters, such as blood flow. Ultrasonographic apparatus suitable for use with the present invention are disclosed in the following U.S. Patents: 4,612,937 to Miller, and 4,334,543 to Fehr. The full disclosures of these two patents are incorporated herein by reference. In a preferred embodiment, the ultrasonography generator may comprise a display 32 for displaying measured hemodynamic parameters and/or expert system 33 capable of analyzing measured hemodynamic parameters. As shown in Figures 2 and 3, the display is located or mounted in a portable unit, such as the ultrasonography generator. As shown in Figure 2, the ultrasonography generator unit 30 is sized to be grasped or held in a user's hand. In the preferred embodiment shown in Figure 3, the system 33 is physically housed or located within the ultrasonography generator unit. In the preferred embodiment shown in Figure 2, the ultrasonography generator unit comprises control mechanisms for regulating the transmission of ultrasound energy. In a preferred embodiment, these control mechanisms include rotatable knobs which may be adjusted to regulate or control the frequency, intensity or wave mode of ultrasound energy emitted by the ultrasonosgraphy generator. The expert system is capable of comparing one or more measured hemodynamic parameters to predetermined parameter limits, such as maximum blood pressure or maximum blood temperature. The expert system is further capable of generating an instruction to the user to stop ultrasound therapy if predetermined parameter limits are exceeded. These instructions may be generated via the display on the ultrasonography generator or by other visual or audible means of communication. The display of instructions stored in the expert system is an example of the ability of the display to allow the user to view stored information.

## REMARKS

This application is a continuation of application serial no. 09/732,274, which is a divisional of application serial no. 09/315,867 ("the '867 Application") which issued as U.S.



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Patent No. 6,221,021 ("the '021 Patent"). All of the amendments made to the specification herein were made and entered by the Patent Office during the prosecution of the '021 Patent. For the convenience of the Examiner, a true and correct copy of the amendment from the prosecution history of the '021 Patent, corresponding to the above amendment is attached as Exhibit A. All of the language which Applicant proposed adding by amendment, appears in the '021 Patent, as summarized in the table below.

| Amended Paragraph No. | Location of Language Added In Amended Paragraph in the '021 Patent |
|---|---|
| [0025] | Col 4, lines 35-39; and 47-50 |
| [0026] | Col 4, line 54 |
| [0029] | Col. 5, lines 20-22 |
| [0030] | Col. 5, lines 28-31 |
| [0033] | Col. 5, lines 63-67 |
| [0034] | Col. 6, lines 16-30, and 37-39 |

The specification has been amended, as explained above. No new matter has been added. Applicant respectfully requests that these amendments be entered.

Respectfully submitted,

12-26-02
Date

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APPENDIX

[0025] The apparatus of the present invention comprises an ultrasound generator [8] 9 and a portable housing 10 coupled to the ultrasound generator, as shown in Figure 2. As shown in Figure 2, control mechanisms for regulating the transmission of ultrasound energy from the ultrasound generator are mounted on body 9, which is sized to be grasped or held in a user's hand. In a preferred embodiment, these control mechanisms include knob-like fixtures 6-7 which may be adjusted to regulate or control the frequency or intensity of ultrasound energy emitted by the ultrasound generator. The portable housing comprises a fist transducer mounting assembly 18. In a preferred embodiment, the first transducer mounting assembly is curved. An ultrasound trigger 11 is mounted in the housing and is electrically coupled to the generator. The ultrasound trigger 11 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasound source or emitters , as shown in Figures 2 and 3

[0026] In a preferred embodiment, the ultrasound generator is capable of selectively generating pulsed or continuous wave ultrasound energy. The selective generation may be accomplished by a control knob or switch [7] 8, as shown in Figure 2. In a preferred embodiment, the ultrasound generator further comprises frequency controls 6 and intensity controls 7, as shown in Figure 2. In a preferred embodiment, the ultrasound generator is capable of generating ultrasound energy within a frequency range of 1.8-3.5 MHz and within an intensity range of 1.0-2.0 watts/square centimeter.

[0029] The apparatus and method of the present invention may be practiced by the patient, after proper training, without assistance from another person. In the preferred embodiment shown in Figure 2, the portable housing has a pistol type grip, thereby allowing the user to operate the trigger or triggers with one hand, while manipulating the position adjuster with the other hand, as needed to maintain a suitable ultrasound coupling during penile expansion. As shown in Figure 2, the portable housing 10 is sized to be grasped or held in a user's hand. The placement of the triggers and axial position adjuster on opposite sides of the housing facilitates the user's ability to easily use both hands to simultaneously manipulate the trigger and the position adjuster.

[0030] In a preferred embodiment, the invention further comprises [an] a second transducer



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mounting assembly 24 mounted across from the first transducer mounting assembly. As shown in Figure 2, the position adjuster permits the distance between housing 10 and mounting assembly 24 to be adjusted by the user using one hand. In the preferred embodiment shown in Figure 2, the mounting assembly 24 is moveably connected to the housing 10. In a preferred embodiment, the second transducer mounting assembly is mounted in alignment with the first transducer mounting assembly. In another preferred embodiment, the second transducer mounting assembly is curved. The second transducer mounting assembly is coupled to the position adjuster. In a preferred embodiment, the radii of curvature of the first and second transducer mounting assemblies are sized such that the first and second transducers can be coupled to the outer surface of a penis.

[0033] In the preferred embodiments shown in Figures 2-3, the invention further comprises an ultrasonography generator 30 connected to at least one transducer in each transducer mounting assembly and an ultrasonography trigger 12 mounted in the portable housing and connected to the ultrasonography generator. The ultrasonography trigger 12 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasonography generator and through the ultrasound source or emitters, as shown in Figures 2 and 3. In a preferred embodiment the ultrasonography generator and the ultrasound generator are each connected to at least two ultrasound transducers in each of the transducer mounting assemblies. In a preferred embodiment the ultrasonography generator is a doppler ultrasound unit.

[0034] The ultrasonography generator is suitable for monitoring penile hemodynamic parameters, such as blood flow. Ultrasonographic apparatus suitable for use with the present invention are disclosed in the following U.S. Patents: 4,612,937 to Miller, and 4,334,543 to Fehr. The full disclosures of these two patents are incorporated herein by reference. In a preferred embodiment, the ultrasonography generator may comprise a display 32 for displaying measured hemodynamic parameters and/or expert system 33 capable of analyzing measured hemodynamic parameters. As shown in Figures 2 and 3, the display is located or mounted in a portable unit, such as the ultrasonography generator. .As shown in Figure 2, the ultrasonography generator unit 30 is sized to be grasped or held in a user's hand. In the preferred embodiment shown in Figure 3, the system 33 is physically housed or located within the ultrasonography

generator unit. In the preferred embodiment shown in Figure 2, the ultrasonography generator unit comprises control mechanisms for regulating the transmission of ultrasound energy. In a preferred embodiment, these control mechanisms include rotatable knobs which may be adjusted to regulate or control the frequency, intensity or wave mode of ultrasound energy emitted by the ultrasonosgraphy generator. The expert system is capable of comparing one or more measured hemodynamic parameters to predetermined parameter limits, such as maximum blood pressure or maximum blood temperature. The expert system is further capable of generating an instruction to the user to stop ultrasound therapy if predetermined parameter limits are exceeded. These instructions may be generated via the display on the ultrasonography generator or by other visual or audible means of communication. The display of instructions stored in the expert system is an example of the ability of the display to allow the user to view stored information.

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

I hereby certify that this paper along with any referred to as being attached or enclosed, is being forwarded to the Commissioner of Patents, Washington, D.C. 20231, via U.S. Postal Service, first class mail, postage prepaid on December 26, 2002.

Richard T. Redano

Richard T. Redano



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# Exhibit A to EXHIBIT 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Applicants: | Richard T. Redano | § | Examiner: F. Jaworski |
| | | § | |
| Serial No.: | 09/315,867 | § | Group Art Unit: 3737 |
| | | § | |
| Filed: | 05/20/99 | § | |
| | | § | Atty Docket: REDA-004 |
| Title: | Method And Apparatus For Penile Hemodynamic Stimulation, Monitoring And Drug Delivery Acceleration | § | |

**AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated February 4, 2000, please amend the above identified application as indicated below.

## I. IN THE CLAIMS

Please cancel claims 3-7, 10, 13, 17, and 19-20. Please amend claims 1, 2, 12, 14, and 15, as shown below.

1. (Amended) A method for [stimulating hemodynamic activity within] injecting ultrasound energy into a penis, comprising:

a. coupling an ultrasound source to a lesion free region of the outer surface of a penis; and

b. transmitting ultrasound energy through a lesion free region of the penis and into the corpora cavernosum of the penis [at a sufficient frequency and intensity to increase hemodynamic flow within the penis] by actuating a triggering mechanism mounted in a housing sized to be grasped in a user's hand.



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2. (Amended) The method of claim 1, wherein [the source of ultrasound energy comprises at least] said transmitting is performed by two ultrasound transducers placed on opposite sides of the penis.

12. (Amended) A method for accelerating the delivery of a vasodilating agent in a patient's body to produce a penile erection comprising:

a. ingesting a vasodilating agent into the body at a point of ingestion external to the penis;

b. coupling an ultrasound source to a lesion free region of the outer surface of a penis; and

c. transmitting ultrasound energy through a lesion free region of the penis and into the corpora cavernosum of the penis at a sufficient frequency and intensity to increase hemodynamic flow within the penis.

In claim 14, line 1, replace "transdermal' with --oral--.

15. (Amended) The method of claim 12, wherein said ingesting a vasodilating agent is accomplished by ingesting a PDE inhibitor or an alpha adrenergic blocker.

Please add claims 21- 37, as shown below.

21. A method for accelerating the delivery of a vasodilating agent to a patient's penis, comprising:

a. ingesting a vasodilating agent into the body at a point of ingestion external to the penis; and

b. increasing hemodynamic activity within the patient's body.

22. An apparatus for a user to monitor hemodynamic parameters when the user is grasping the apparatus housing in one hand, comprising:

a. an ultrasonography generator comprising a display capable of displaying at least one



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measured hemodynamic parameter;

b. a portable housing sized to be grasped in a user's hand

c. a triggering mechanism mounted in said housing and connected to said generator; said triggering mechanism being capable of actuating said generator;

d. a transducer mounting assembly moveably connected to said housing such that the distance between said assembly and said housing can be adjusted by a user using only one hand, said assembly comprising a curved surface; and

e. at least two ultrasound emitters mounted in said assembly along a curved path and connected to said triggering mechanism.

23. The apparatus of claim 22, wherein said generator is a doppler ultrasound unit.

24. The apparatus of claim 23, wherein said display is capable of displaying blood flow.

25. The apparatus of claim 22, wherein said generator further comprises a system capable of analyzing measured hemodynamic parameters, said system being physically located within said generator.

26 The apparatus of claim 25, wherein said system is capable of generating a signal to control the operation of said generator.

27 The apparatus of claim 26, wherein said system is further capable of generating an instruction to the user.

28. The apparatus of claim 25, wherein said system is capable of transmitting measured hemodynamic data to a location that is remote from said apparatus.

29. The apparatus of claim 22, said generator is a portable unit comprising at least three rotatable control knobs for regulating the transmission of ultrasound energy.



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30. An apparatus capable of monitoring hemodynamic parameters, comprising:

a. a portable body sized to be hand held;

b. an ultrasonography generator mounted in said body and capable of measuring one or more hemodynamic parameters, said generator comprising a display capable of displaying at least one measured hemodynamic parameter;

c. a curved transducer mounting assembly moveably connected to said body such that the distance between said assembly and said housing can be adjusted by a user using only one hand;

d. at least two ultrasound emitters mounted in said assembly along a curved path; and

e. a triggering mechanism connected to said emitters and to said generator.

31. The apparatus of claim 30, further comprising at least two rotatable control mechanisms mounted on said body and coupled to said generator to regulate the transmission of ultrasound energy.

32. The apparatus of claim 31, wherein said body comprises at least three rotatable control knobs.

33.. The apparatus of claim 30, wherein said generator is a doppler ultrasound unit.

34. The apparatus of claim 33, wherein said display is capable of displaying blood flow.

35. The apparatus of claim 30, wherein said generator further comprises a system capable of analyzing measured hemodynamic parameters, said system being housed within said body.

36. The system of claim 35, wherein said system is further capable of generating an instruction to the user.

37. The apparatus of claim 36, wherein said system is capable of transmitting measured



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hemodynamic data to a location that is remote from said apparatus.

## II. IN THE SPECIFICATION

At page 6, line 19, change "8" to --9--.

At page 6, line 20, before "The", insert --As shown in Figure 2, control mechanisms for regulating the transmission of ultrasound energy from the ultrasound generator are mounted on body 9, which is sized to be grasped or held in a user's hand. In a preferred embodiment, these control mechanisms include knob-like fixtures 6-7 which may be adjusted to regulate or control the frequency or intensity of ultrasound energy emitted by the ultrasound generator.--.

At page 6, line 23, after "generator.", insert--The ultrasound trigger 11 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasound source or emitters, as shown in Figures 2 and 3.--.

At page 6, line 26, change "7" to --8--.

At page 7, line 20, before "The", insert--As shown in Figure 2, the portable housing 10 is sized to be grasped or held in a user's hand. --.

At page 7, line 23, before "second", change "an" to --a--.

At page 7, line 24, before "In" insert --As shown in Figure 2, the position adjuster permits the distance between housing 10 and mounting assembly 24 to be adjusted by the user using one hand. In the preferred embodiment shown in Figure 2, the mounting assembly 24 is moveably connected to the housing 10.--.

At page 8, line 16, before "In" insert --The ultrasonography trigger 12 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasonography generator and through the ultrasound source or emitters, as shown in Figures 2 and 3.--.

At page 8, line 26, before "The", insert--As shown in Figures 2 and 3, the display is located or mounted in a portable unit, such as the ultrasonography generator. As shown in Figure 2, the ultrasonography generator unit 30 is sized to be grasped or held in a user's hand. In the preferred embodiment shown in Figure 3, the system 33 is physically housed or located within the ultrasonography generator unit. In the preferred embodiment shown in Figure 2, the ultrasonography



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generator unit comprises control mechanisms for regulating the transmission of ultrasound energy. In a preferred embodiment, these control mechanisms include rotatable knobs which may be adjusted to regulate or control the frequency, intensity, or wave mode of ultrasound energy emitted by the ultrasonography generator. --.

At page 9, line 3, after "communication." insert --The display of instructions stored in the expert system is an example of the ability of the display to allow the user to view stored information.--

At page 10, line 25, before "In", insert--Transmucosal, intranasal, oral, and rectal ingesting are examples of ingesting that occur at a location that is external to, and other than, the penis.--.

At page 11, line 1, after "1B.", insert— Because the ultrasound source is coupled to a lesion free region of the outer surface of the penis, ultrasound energy transmitted from the source is transmitted through the lesion free region of the penis. This step is a preferred embodiment of increasing hemodynmic activity within the patient's body.--.

## III. REMARKS

The specification and claims have been amended for the purposes of explication and clarity. No new matter has been added. Applicant respectfully requests that these amendments be entered.

### A. The Section 112 Rejections

In the Office Action, claims 1-17 were rejected under 35 U.S.C.112 for indefiniteness. Claims 3-7, 10, 13, and 17 have been canceled. Claims 1 and 12 have been amended to recite that the transmission occurs through a lesion free region of the penis. Additionally, claim 12 has been amended to recite "in a patient's body" in the preamble of the claim. Applicant respectfully submits that these amendments render the rejection of claims 1 and 12 moot.

The limitations added by claims 2 and 15 have been amended, thereby rendering the Section 112 rejection of these claims moot.

### B The Section 103 Rejection of Claims 1, 4, 8-9, 11, 12, 14, and 17

In the Office Action Claims 1, 4, 8-9, 11, 12, 14, and 17 were rejected under 35 U.S.C. 103 as being obvious in view of Fahim in combination with Foldvari. Claims 4 and 17 have been canceled



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in order to reduce the total number of claims in this application.. Applicant respectfully submits that claims 1, 8-9, 11-12, and 14 are not obvious in view of these references for the following reasons:

1. Fahim teaches away from the method of the present invention; and
2. The cited references do not disclose all of the limitations of claim 1.

These arguments are set out in detail below.

1. Fahim Teaches Away From The Method of The Present Invention

Claims 1 and 12, as amended, are expressly limited to a method comprising (1) coupling an ultrasound source to a lesion free region of the outer surface of a penis, and (2) transmitting ultrasound energy through a lesion free region of the penis. Fahim does not teach or suggest these limitations. To the contrary, Fahim teaches away from these limitations. Fahim is directed to "a method and composition for the treatment of Herpes Simplex Type 1 and Type 2 lesions." (Emphasis Added; See Abstract). Fahim further states:

> More particularly the present invention relates to a method for applying an effective antiviral drug to Herpes Simplex lesions by ultrasound and to the composition thereof.

(Emphasis Added; Col. 1, ll 10-13). Because Fahim repeatedly teaches away from the "lesion free" limitations of claims 1 and 12, the suggested combination of references does not obviate claims 1, 12 or any claims depending therefrom.

Claims 1 and 12 are also limited to a method comprising the limitation of "transmitting ultrasound energy . . . into the corpora cavernosum." Fahim does not teach or suggest this limitation. To the contrary, Fahim teaches away from this limitation. Fahim is directed to a method of treating Herpes Simplex lesions by massaging a medication into the lesion "with ultrasound vibration." (See Abstract).

Fahim discloses that "in males, genital herpes usually consists of vesicles on the glans of the penis or on the penis." (Emphasis Added; Col. 1; ll 52-54). The "glans of the penis" or the surface of the penis is not the corpora cavernosum. Fahim teaches that the vibration energy of the ultrasound is imparted "on the glans of the penis or on the surface of the penis." This teaches away from the "corpora cavernosum" limitation of claims 1 and 12. For this additional reason, the cited combination of references do not obviate claims 1, 12, or any claims depending therefrom.



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2. The Cited References Fail To Disclose All The Limitations Of Claim 1

In an obviousness rejection, the claimed invention must be evaluated "as a whole". *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1479-'80 (Fed. Cir. 1998). Claim 1, as amended, comprises the limitation of "by actuating a triggering mechanism mounted in a housing sized to be grasped in a user's hand." The cited combination of references fail to disclose this limitation of claim 1. Thus, the cited combination of references do not obviate the invention defined in claim 1, "as a whole."

C. The Section 103 Rejection of Claim 2

In the Office Action, claim 2 was rejected as being obvious in view of Fahim and Foldvari, as applied to claim 1, and further in view of Itoh. Claim 2 depends from claim 1. Accordingly, claim 2 is not obviated by this combination of references for all of the reasons that claim 1 was not obviated by Fahim and Foldvari, as set forth is Section B, above. Additionally, claim 2 has been amended to incorporate the limitation of transducers being "placed on opposite sides of the penis", from claim 3. Claim 3 was not rejected in view of Fahim, Foldvari, and Itoh. Thus, claim 2, as amended, is not obviated by the suggested combination of references.

D. The Section 103 Rejection of Claim 5-6

In the Office Action, claims 5-6 were rejected as being obvious in view of Fahim and Foldvari, as applied to claim 1, and further in view of Balamuth. Claims 5-6 have been canceled in order to reduce the total number of claims in this application. Accordingly, this rejection is rendered moot.

E. The Double Patenting Rejection of Claims 1-3, 8-9, and 11

In the Office Action, claims 1-3, 8-9 and 11 were rejected under the judicially created doctrine of obviusness type double patenting in view of USPN 5,947,901 ("the '901 Patent") and Gerstenberg. Applicant herewith files a terminal disclaimer, disclaiming any term of any patent issuing from this application beyond the term of USPN 5,947,901. Applicant respectfully submits that this terminal disclaimer renders this rejection moot.



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F. The Double Patenting Rejection of Claims 18-20

In the Office Action, claims 18-20 were rejected under the judicially created doctrine of obviousness type double patenting in view of claims 1,6-7 of USPN 5,931,783 ("the '783 Patent"). Applicant herewith files a terminal disclaimer, with traverse (see next paragraph), disclaiming any term of any patent issuing from this application beyond the term of the '783 Patent. Applicant respectfully submits that this terminal disclaimer renders this rejection moot, but Applicant traverses this rejection, as set forth below, for the purposes of precluding prosecution history estoppel, based upon the filing of this terminal disclaimer.

During the prosecution of the parent application (Serial No. 08/926,209), upon which this application claims priority, Examiner Ruth Smith rejected several of Applicant's pending claims under 35USC112, for failing "to enable one skilled in the art . . . to make and/or use the invention" comprising claim limitations directed toward injecting ultrasound energy at a sufficient frequency and intensity to increase hemodynamic flow within the penis (see December 9, 1998 Office Action, p 2). Applicant respectfully submits that it is inconsistent with Examiner Smith's Section 112 enablement rejection in the file history of the parent application for the Patent Office to now take the position that it would have at this point been "within the ordinary skill level of the artisan to apply a safe and effective particular frequency and power level for accuracy."

Thus, the doubling patenting rejection of claims 18-20 is legally unsound. Applicant files a terminal disclaimer based on the '783 Patent only because such a terminal disclaimer is believed to be superfluous in view of the facts that (1) Applicant is already filing a terminal disclaimer in view of the '901 Patent, and (2) the '783 Patent issued from a divisional application of the parent application which became the '901 Patent. Thus, by filing a terminal disclaimer in view of the '783 Patent, Applicant believes he is not disclaiming anything that he has not already disclaimed by filing a terminal disclaimer based upon the '901 Patent. By filing a terminal disclaimer based upon the '783 Patent, Applicant believes he is taking a course of action which will avoid delays in prosecuting this application and issuing a patent which may come from this application. Applicant's filing of a terminal disclaimer based upon the '783 Patent in response to the doubling patenting rejection of claims 18-20 is not intended to be construed as an admission by Applicant that this double patenting rejection is substantively meritorious.

## III. CONCLUSION

New claim 21 is directed toward a method for accelerating the delivery of a vasodilating agent to the penis. Support for this claim is found in the specification at pages 10-11.

New claims 22-37 are directed toward various apparatus embodiments of Applicant's invention, as depicted in Figures 2-3 and as described at pages 5-9 of the specification.

Accordingly, Applicant requests a Notice of Allowance of claims 1-2, 8-9, 11-12, 14-16, 18, and 21-37.

Respectfully submitted,

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**CERTIFICATE OF TIMELY MAILING UNDER 37 C.F.R. 1.8(a)**

I hereby certify that this paper, along with any referred to as being attached or enclosed, is being forwarded to the Assistant Commissioner of Patents, Washington, D.C. 20231, via the United Stated Postal Service, first class mail, postage prepaid on MAY 1, 2000.

Richard T Redano



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